February 11, 2003

The University of Utah submits the following comments on U.S. Department of Health and Human Services' (HHS) Interim Final Rule on the Possession, Use and Transfer of Select Agents and Toxins (67 FR 76886-76905). As the University of Utah ranks in the top 35 research institutions in the nation with more than $275 Million in annual external research funding, we hope that our information and suggestions are valuable to Health and Human Services.

73.1 Definitions

We recommend including a definition of "access" to mean: "The ability to gain physical control of select agents and toxins."

We agree with comments made by the Howard Hughes Medical Institution (HHMI) group that the above definition of "access" would minimize uncertainty and help Entities comply with the security, training, and record keeping requirements that rely on "access." The recommended definition would apply to those sections of 42 CFR 73 where "access to a select agent," "access to containers," or "approved for access" are used.

We also agree with HHMI that the term "entry" should replace "access" when a requirement addresses admission to a select agent area by an individual not approved under 73.8. Specifically, "entry" should replace "access" in Sections 73.11(b)(6), 73.13(c) and (e), and 73.14(c)(2). These changes and the above definition would greatly clarify the rules.

73.4 HHS Select Agents and Toxins

We recommend deletion of Cercopithecine herpesvirus 1 (CHV-1) from the HHS list of select agents and toxins. We are in agreement with the rationale provided in the HHMI response.

73.7 Registration

73.7(b) (2) (viii)
We recommend deleting this provision from the Final Rule

73.7 (c)
We recommend that HHS and USDA create a single office to receive all registrations for possession, use, and transfer of select agents and toxins covered by the requirements of 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121

73.7 (d)

We recommend deleting the word "protocol" from the third sentence in this provision and revising the sentence to read, "This includes modifications to the list of individuals approved under 73.8 and changes in the biosafety and laboratory information and objectives of the work with select agents and toxins"

Protocols can change frequently in active research programs without altering the relevant biosafety and laboratory information or the objectives of the work. A requirement for prior approval from HHS to modify a protocol before implementing the protocol change will predictably hinder research.

73.7 (f)

We recommend that an entity have the option to apply for a single certificate of registration to cover activities at all buildings on a campus or site under the control and authority of the Responsible Official.

This would include both contiguous and dispersed sites within a local geographical area. Separate registrations for each general physical location (defined as "a building or a complex of buildings at a single mailing address") is overly burdensome in terms of staffing, training, record keeping, and naming of Responsible Officials. 73.9 Responsible Official, authorizes the Responsible Official to identify one or more Alternate Responsible Officials to provide coverage for and assist the Responsible Official. This nullifies the argument that separate registrations are necessary to ensure against over-extending the Responsible Official. In addition, administrative and control functions at research and academic institutions, including environmental health and safety and security programs, are efficiently managed by a centralized department responsible for more than one physical location.

73.7 (g)

We recommend that the certificate of registration be valid up to five years.

The change would make this provision consistent with 73.8 (f) which sets a five-year expiration on the security risk assessment. This change would simplify paperwork logistics for the entity and reduce the cost to the government for the registration process.

73.8 Security Risk Assessment

73.8 (c)

We recommend that the Final Rule define the information the entity must submit to the Attorney General for the security risk assessment.

73.8 (e)

We recommend that the Final Rule provide provisions for an entity or individual to appeal a security determination or seek an exemption allowing conditional access to select agents and toxins.

73.8 (f)

We recommend that the HHS Secretary's approval for an individual to access select agents and toxins be portable from entity to entity, from location to location, and from project to project for the duration of the valid period.

73.10 Safety

We recommend that the HHS Secretary not incorporate the Biosafety in Microbiological and Biomedical Laboratories and the NIH Guidelines for Research Involving Recombinant DNA Molecules as requirements in the Final Rule. We recommend that the Final Rule recognize these guidelines as authoritative codes of practice that entities should consider in developing and implementing a performance-based safety plan for the safe possession and use of select agents. In addition, the Final Rule should reference the performance-based OSHA Hazardous Chemicals in Laboratories Standard, 29 CFR Part 1910.1450, as the regulatory requirement for possession and use of toxins.

Incorporating these guidelines as prescriptive requirements in the Final Rule would compromise their value and intent, and weaken the concept of a code of practice embraced by scientists, and health and safety professionals. The guidelines would soon lose current relevance because revisions would require rulemaking, which is a time-consuming and costly process.

73.10 (d)

We recommend that the CDC provide the comments it received on 42 CFR Part 73, 73.10 (d) to the National Research Council and the NIH Recombinant DNA Advisory Committee for their consideration. The CDC should not list new experiments in 73.10 (d) without broad scientific review and guidance.

73.11 Security

We recommend that the security provisions provide performance-based requirements consistent with the approach used to establish the requirements for the safety provisions in 42 CFR Part 73.10. This approach should convey the appropriateness of establishing a tiered system of security controls that is commensurate with the risk such agent or toxin poses to public health and safety (including the risk of use in domestic or international terrorism).

73.12 Emergency Response

73.12 (a)

We recommend revising the first sentence of this provision to read, "An entity subject to the provisions of this Part, must develop and implement an emergency plan that meets the applicable requirement of the OSHA Hazardous Chemicals in Laboratories Standard, 29 CFR Part 1910.1450, and the OSHA Emergency Action Plans Standard, 29 CFR Part 1910.38

Work conducted with hazardous materials in academic and research institutions is appropriately governed by the OSHA Hazardous Chemicals In Laboratories Standard, 29 CFR 1910.1450, not by the OSHA Hazardous Waste Operations and Emergency Response Standard, 29 CFR Part

1910.120, which provides oversight of large scale hazardous materials spill response and remediation. Chemical Hygiene Plans, developed in accordance with the OSHA Hazardous Chemicals in Laboratories Standard, 29 CFR Part 1910.1450, addressed laboratory-scale spill and release procedures. The OSHA Emergency Action Plans Standard, 29 CFR Part 1910.38 more appropriately addresses an institution-wide emergency response plan.

73.13 Training

73.13 (a)

We recommend revising this provision in its entirety to read as the HHMI group advised: "An entity required to register under this Part must provide information and training on safety and security for working with select agents and toxins to each individual approved for access under 73.8 and each unapproved individual working in or visiting areas where select agents and toxins are handled or stored. An entity may modify the training according to the needs of the individual, the work they will do and their potential exposure. The training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard, 29 CFR Part 1910.1030."

73.17 Notification of Theft, Loss, or Release

73.17 (d)

We recommend revising the first sentence of this provision to read as the HHMI group advised: "The entity shall immediately notify the HHS Secretary and State and local public health agencies of any release of a select agent or toxin causing occupational exposure or release outside of the biocontainment area of a registered entity."

This language is in line with the intent of the Standard. Immediate reporting of a manageable spill would be wasteful of resources, increase apprehension and fear, and serve no benefit to public health.

Thank you for the opportunity to comment on this proposal and for considering our comments. Should you have questions, please contact Marty Shaub or Michele Johnson at 801-581-6590.

Sincerely,

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